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10/763,815	01/22/2004	Tette van der Lende	2183-6293US	4997

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,815

Applicant(s)

VAN DER LENDE, TETTE

Examiner

Casey Hagopian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 5-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/5/06.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks and Information Disclosure Statement filed 7/5/2006. Claim 4 has been cancelled; thus claims 1-3 and 5-20 are currently pending.

MAINTAINED REJECTIONS

The following rejections are maintained:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 2002/0051844 A1) in view of Mahan, "Digestibility of soybean meals collected at four periods from a soybean processor (Cargill) in Ohio".

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Wilson teaches animal food compositions and methods for increasing the reproductive performance of breeding populations of swine (abstract). Wilson also teaches incorporating any animal feed blend known in the art including rapeseed meal, cottonseed meal, soybean meal, and cornmeal as well as amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine (paragraph 0031, Examples). Wilson also teaches several methods of administration ranging from feeding the composition to the animals daily for their lifetime, to feeding the composition to an animal before and/or during pregnancy and/or during lactation, and so on (paragraph 0030).

Wilson does not teach specific amounts of the amino acids.

Mahan teaches that soybean meal, a well-known feed material, naturally comprises amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine and provides percentage amounts for each amino acid (Table 2). Mahan also teaches that soybean meal naturally contains 0.20% calcium. One of ordinary skill in the art would have been motivated to optimize the particular amounts of amino acids in the composition taught by Wilson by way of routine experimentation. Absent of unexpected results, a practitioner would reasonably expect an animal feed composition to provide the same result as suggested by Wilson; to increase the reproductive performance of breeding populations of swine. Thus in Wilson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the animal feed composition.

Response to Arguments

5. Applicant's arguments, see pages 6-7, filed 7/5/2006, with respect to the rejections of claims 1-20 under 35 USC 112, 1st and 2nd paragraphs have been fully considered and are persuasive. The amendments to claims 1- 20 render the rejections moot, thus the rejections of claims 1-20 under 35 USC 112, 1st and 2nd paragraphs have been withdrawn.

6. Applicant's arguments, see pages 7-8, filed 7/5/2006, with respect to the rejection of claims 4, 5, 7 and 8 under 35 USC 112, 2nd paragraph have been fully considered and are persuasive. The amendments to claims 4, 5, 7 and 8 render the rejection moot, thus the rejection of claims 4, 5, 7 and 8 under 35 USC 112, 2nd paragraph has been withdrawn.

7. Applicant's arguments, see pages 8-9, filed 7/5/2006, with respect to the rejection of claims 1-20 under 35 USC 103 have been fully considered but they are not persuasive.

Applicant argues that Wilson is directed to the effect of ω -3 fatty acids and does not suggest the effect of arginine on the reproductive performance on swine. Applicant further states that Wilson does not mention specific or relative amounts of amino acids in the animal feed. Applicant also argues that Mahan teaches a weight ratio between arginine and lysine to be lower than the claimed 1.5 and accordingly, there is no suggestion or motivation to modify or combine the references. Applicant further points to a report from the NRC that states that "swine during pregnancy synthesize all the necessary arginine" and that "excessive supplements of arginine are undesirable as it

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can reduce feed intake and reduce growth” thereby one of ordinary skill in the art would not have reasonable expectation of success by increasing the arginine content of the feed.

In response to applicant’s arguments, the examiner respectfully points out that claims 1-10 and 20 are directed to a product and do not contain any limitation directed to the reproductive performance of swine. However assuming arguendo, any recitation of an intended use does not alone show patentable distinction. A recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim. As for the method claims (claims 11-19), Wilson teaches a method for increasing the reproductive performance of breeding populations of swine comprising administering compositions that include animal feed blends such as rapeseed meal, cottonseed meal, soybean meal, and cornmeal (that contain amino acids naturally as evidenced by Mahan) and further optionally including additional amino acids (see 103 Rejection). Claim 11 currently reads, “A method for increasing the breeding productivity of an animal, said method comprising providing a diet to at least one gestating animal resulting in a daily dosage of 200-1300 mg arginine per kg body weight of said at least one gestating animal.” It should be noted that the instant claims contain “comprising” open-ended language that allows for other method steps to be included. Wilson teaches the method as claimed, that is, increasing the breeding productivity of an animal by providing a diet to a gestating animal containing arginine.

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Wilson further exemplifies "breeding" formulations comprising soybean meal (SBM), which naturally contains arginine in the Examples section of the patent. While Wilson is silent to the relative or exact amounts of amino acids, Mahan teaches typical percentages of amino acids found in soybean meal. Specifically, Mahan teaches that soybean meal contains 3.56% arginine, 2.97% lysine, 0.65% methionine, 0.76% cysteine, 0.61% tryptophan and 1.83% threonine. As applicant has pointed out, these percentages can be translated to ratios relative to the amount of lysine (i.e. arginine = 1.2; methionine + cysteine = 0.47, tryptophan = 0.21, and threonine = 0.61). While Mahan exhibits ratios for arginine and methionine + cysteine that are less than the claimed ratios, as discussed above, Wilson teaches further adding amino acids to the feed blend. Thus, Wilson teaches including additional amino acids to which is already naturally occurring in a typical feed such as soybean meal. Furthermore, it is within one skilled in the art to optimize a composition by altering formulations through routine experimentation. In regards to the NRC report, the examiner finds this argument unpersuasive for two main reasons: 1) the art relied upon in the 103 rejection does not discuss any harmful effects of arginine that would discourage one of ordinary skill in the art to add additional amounts of arginine to a feed blend and in fact, conversely teaches to add additional amino acids to feed blends that already naturally contain amino acids; and 2) Baba et al. (USPN 4,241,082) teaches compositions comprising L-dopa and amino acids, preferably L-arginine, for the use of promoting reproductive ability in animals. Baba specifically teaches that the reproductive activity of L-dopa is significantly enhanced by a combination thereof with one or more amino acids selected

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from the group consisting of L-arginine, L-ornithine, L-lysine, D-phenylalanine, L-glutamic acid and γ -aminobutyric acid (column 2, lines 35-60). Baba further teaches that composition contains L-dopa in the amount of 0.2 mg to 50 mg per kg body weight and that L-arginine is included in the range of 1/10 to 10 times the amount of L-dopa (column 3, lines 42-60). In other words, L-arginine is included in the amount of .02 mg to 500 mg per kg body weight. These teachings of Baba refute the NRC reports findings and not only teach that a composition comprising arginine and L-dopa enhance and promote reproductive ability in animals but also teaches a range amount of arginine that is well within the claimed range of 200-1300 mg/kg. For these reasons, the examiner respectfully disagrees with applicant's position and as such the rejection under 35 USC 103 is maintained.

Pertinent Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Chalupa et al. (USPN 3,949,090) teaches animal feed compositions and methods thereof comprising well-known feed products including casein, soybean meal, and fish meal as well as amino acids including cysteine, methionine, lysine, threonine, arginine, and tryptophan and amounts thereof (columns 3-4).

Baba et al. (USPN 4,241,082) teaches animal feed compositions and methods thereof (i.e. promoting reproduction) comprising L-dopa and one or more amino acids, preferably L-arginine, as well as amounts and ratios thereof.

Conclusion

9. All claims have been rejected; no claims are allowed.
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

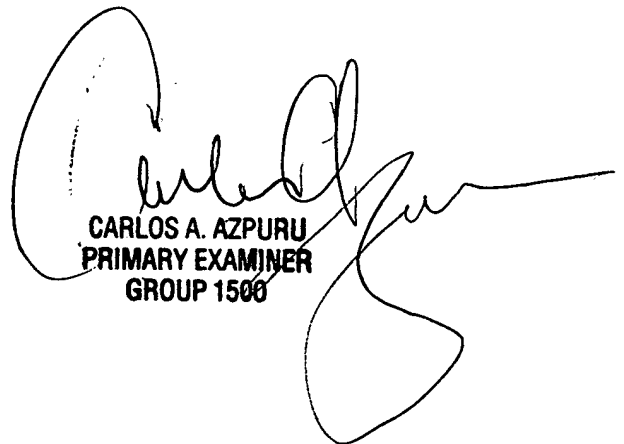
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian
Examiner
Art Unit 1615



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